UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL SIPLE, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

NEOVASC INC., FRED COLEN, and CHRISTOPHER CLARK,

Defendants.

Case No.

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiff Daniel Siple ("Plaintiff"), individually and on behalf of all others similarly situated, by and through Plaintiff's attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, the investigation conducted by Plaintiff's counsel, which includes, without limitation: (a) review and analysis of regulatory filings made by Neovasc Inc. ("Neovasc" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Neovasc; and (c) review of other publicly available information concerning Neovasc.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities that purchased or otherwise acquired Neovasc securities between October 10, 2018 and October 27, 2020, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Neovasc is a specialty medical device company that develops, manufactures, and markets products for cardiovascular diseases, including the Tiara technology and the Reducer. The Company's Reducer is a medical device that treats refractory angina by altering blood flow in the heart's circulatory system.

3. In December 2018, the Company filed a Q-Sub submission to the U.S. Food and Drug Administration ("FDA") that contained safety and efficacy results from Neovasc's clinical studies, as well as supporting data from peer-reviewed journals.

4. On February 20, 2019, Neovasc announced that, despite "Breakthrough Device Designation," the FDA review team recommended that the Company collect further pre-market blinded data prior to submitting a Pre-Market Approval ("PMA") application.

5. On November 1, 2019, the Company announced that it would submit a PMA application for the Reducer without gathering further evidence, against the FDA's recommendation. Neovasc claimed that "the clinical evidence already available will be sufficient to not further delay the availability of this Breakthrough medical device for the treatment of U.S. patients."

6. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (i) Neovasc had overstated the viability of U.S. approval of the Reducer based on its "Breakthrough Device Designation" and prior studies supporting the Reducer's efficacy and safety; (ii) the results of Neovasc's clinical studies used to support approval for the Reducer in the U.S. contained imbalances in missing information present in the control group versus the treatment group, including significant missing information for secondary endpoints but none for the primary endpoint; (iii) the imbalance in missing information indicated that control subjects were aware of their treatment assignment (not blinded) and less inclined to participate in additional data collection; (iv) blinding is critical when studying a placebo-responsive condition such as angina; (v) the lack of blinding assessment made the primary endpoint difficult to interpret; (vi) as a result of the foregoing, the FDA was reasonably likely to require additional premarket clinical data; (vii) as a result, the Company's PMA for Reducer was unlikely to be approved without additional clinical data; and (viii) as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

7. On October 28, 2020, before the market opened, the Company announced that an FDA advisory panel voted overwhelmingly against the safety and effectiveness of the Reducer. The panel noted concerns with the Company's clinical data, including "that the lack of blinding assessment made the primary endpoint difficult to interpret." As a result, the panel reached a consensus "that additional premarket randomized clinical data was necessary."

8. On this news, the Company's common share price fell $0.77 per share, or 42%, to close at $1.06 per share on October 28, 2020, on unusually heavy trading volume.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

14. Plaintiff , as set forth in the accompanying Certification, incorporated by reference herein, purchased Neovasc securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

15. Defendant Neovasc is incorporated under the laws of Canada with its principal executive offices located in British Columbia, Canada. Neovasc's common shares trade in an efficient market on the NASDAQ exchange ("NASDAQ") under the symbol "NVCN."

16. Defendant Fred Colen ("Colen") was the Company's Chief Executive Officer at all relevant times.

17. Defendant Christopher Clark ("Clark") was the Company's Chief Financial Officer at all relevant times.

18. Defendants Colen and Clark (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

19. Neovasc is a specialty medical device company that develops, manufactures, and markets products for cardiovascular diseases, including the Tiara technology and the Reducer. The Company's Reducer is a medical device that treats refractory angina by altering blood flow in the heart's circulatory system.

Materially False and Misleading Statements Issued During the Class Period

20. The Class Period begins on October 10, 2018, when Neovasc announced that the Reducer was granted "Breakthrough Device Designation" from the FDA. In a press release, the Company stated, in relevant part:

> Neovasc . . . today announced that the [FDA] has granted Breakthrough Device designation to the Neovasc Reducer™ (the "Reducer"), a medical device for the treatment of refractory angina, which is not currently approved for commercial sale in the U.S.
>
> The FDA grants Breakthrough Device designation in order to expedite the development and review of a device that demonstrates compelling potential to provide a more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases. To qualify as a Breakthrough Device, there must either be no FDA approved treatments presently available, or the technology must offer significant advantages over existing approved alternatives.
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> "We are pleased that the FDA has approved our request for Breakthrough Device designation for the Reducer. We will now start a process of further discussions and filings with the FDA, to obtain further guidance as to the regulatory pathway for entrance into the U.S. market. ***This designation supports our belief that this technology offers a significant benefit to patients suffering from refractory angina***," commented Fred Colen, Neovasc's President and Chief Executive Officer. "We look forward to working closely with FDA through this regulatory process."
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> Refractory angina, resulting in continued symptoms despite maximal available medical therapy and without revascularization options, is estimated to affect 600,000 to 1.8 million Americans, with 50,000 to 100,000 new cases per year.

(Emphasis added.)

21. On this news, Neovasc's common share price rose $3.60 per share, or approximately 15%, to close at $28.00 per share on October 10, 2018, on unusually heavy trading volume.

22. In December 2018, the Company filed a Q-Sub submission to the FDA that contained safety and efficacy results from Neovasc's clinical studies, as well as supporting data from peer-reviewed journals.

23. The above statements identified in ¶¶ 20 and 22 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (i) Neovasc had overstated the viability of U.S. approval of the Reducer based on its "Breakthrough Device Designation" and prior studies supporting the Reducer's efficacy and safety; (ii) the results of Neovasc's clinical studies used to support approval for the Reducer in the U.S. contained imbalances in missing information present in the control group versus the treatment group, including significant missing information for secondary endpoints but none for the primary endpoint; (iii) the imbalance in missing information indicated that control subjects were aware of their treatment assignment (not blinded) and less inclined to participate in additional data collection; (iv) blinding is critical when studying a placebo-responsive condition such as angina; (v) the lack of blinding assessment made the primary endpoint difficult to interpret; (vi) as a result of the foregoing, the FDA was reasonably likely to require additional premarket clinical data; (vii) as a result, the Company's PMA for Reducer was unlikely to be approved without additional clinical data; and (viii) as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

The Truth Begins to Emerge

24. On February 20, 2019, during pre-market hours, Neovasc announced that the FDA review team recommended collection of further pre-market blinded data prior to submitting a PMA application. In a press release, the Company stated, in relevant part:

> The Neovasc team, together with two top U.S. Cardiologists, met with the FDA proposing moving forward with a [PMA] submission using the available Neovasc clinical evidence including the prospective, multicenter, randomized, double-blind, sham controlled study assessing the safety and efficacy of the Reducer in 104 patients in the European Union and Canada (COSIRA), a multi-center, multi-country, three-arm observational post market study (REDUCER-I) with currently 189 patients enrolled, and supportive safety and efficacy data from peer-reviewed journals. ***The FDA has now informed Neovasc that, despite "Breakthrough Device Designation", the review team recommends collection of further pre-market blinded data prior to PMA submission***. Through the Sprint discussion process, Neovasc will continue discussions with the FDA and their senior management, to attempt to bring this promising refractory angina device therapy, which has been available to patients in Europe since 2015 with demonstrated quality of life improvement and great safety profile, to U.S. patients as soon as possible.

(Emphasis added.)

25. On this news, Neovasc's common share price fell $0.10 per share, or 1.47%, to close at $6.70 per share on February 20, 2019. Despite this decline in the Company's share price, Neovasc securities continued to trade at artificially inflated prices throughout the remainder of the Class Period as a result of Defendants' continued misrepresentations regarding the viability of U.S. approval of the Reducer based on its "Breakthrough Device Designation" and prior studies supporting the Reducer's efficacy and safety.

26. For example, on November 1, 2019, Neovasc announced that it would submit a full PMA application to the FDA for the Reducer. In a press release, the Company stated, in relevant part:

> Neovasc has been meeting with the FDA to discuss potential options to bring Reducer to the U.S. market. Following the last Sprint discussion held with the FDA on October 9, 2019 and weighing all available options a final decision was made

> by the Company to pursue a full PMA application for this Breakthrough medical device.
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> "We believe that ***the totality of clinical evidence from the COSIRA study, REDUCER-I European Post-Market study (with over 200 of 400 patients enrolled), and multiple independent studies published in peer-reviewed journals, will provide reasonable assurance of safety and effectiveness to support a PMA***. Neovasc plans to submit the PMA application prior to the end of 2019 with a request for an Advisory Panel meeting", said Fred Colen, President and CEO of Neovasc. "While any pathway to U.S. market approval by the FDA carries considerable risk, we believe the full PMA application pathway brings the best chance of success within reasonable cost and time constraints. After evaluating the different options, we concluded that the Humanitarian Use Device ("HUD") pathway would likely not be a viable option based on the definition of an HUD device within the FDA Guidance and that the PMA pathway would be our best option to bring Reducer to the U.S. market to treat refractory angina patients. While an additional post-market study will most likely be needed and the body of real-world evidence continues to grow, ***the Company believes that the clinical evidence already available will be sufficient to not further delay the availability of this Breakthrough medical device for the treatment of U.S. patients***."

(Emphases added.)

27. On November 7, 2019, Neovasc announced its third quarter 2019 financial results in a press release that stated, in relevant part:

> "The third quarter of 2019 was another one of significant progress for the Company as we build the clinical data around Tiara and expand our Reducer commercial presence" said Fred Colen, President and Chief Executive Officer of Neovasc. "We continued to add to our sales team, and reached an important milestone with close to 200 patients being implanted with Reducer in Germany just after the end of the quarter. ***Additionally, we have taken concrete steps on the path to approval in the U.S. market. To that end, we decided to submit a full PMA application to the FDA before the year is out. We believe that the totality of clinical data available now, from the COSIRA study, REDUCER-I European Post-Market study (with over 200 of 400 patients enrolled), and multiple independent published studies, should provide reasonable assurance of safety and effectiveness to support a PMA***."

(Emphasis added.)

28. On December 31, 2019, Neovasc announced that it had submitted its PMA for the Reducer to the FDA. In a press release, the Company stated, in relevant part:

> Neovasc . . . today announced the submission of a [PMA] to the [FDA] for its Neovasc ReducerTM ("Reducer") medical device for the treatment of refractory angina. The submission also includes a request for an Advisory Panel meeting.
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> "This submission marks an important milestone in our effort to bring Reducer to the U.S. market, where it is estimated that there are up to 1.8 million patients with refractory angina," said Fred Colen, President and Chief Executive Officer of Neovasc. "These patients have traditionally had no options – they are either unsuitable for revascularization or continue to suffer with angina following revascularization procedures. The Reducer provides potential relief of angina symptoms by altering blood flow within the myocardium of the heart and increasing the perfusion of oxygenated blood to ischemic areas of the heart muscle."
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> The PMA for Reducer includes clinical data from the COSIRA 104 patient randomized, double-blind, sham-controlled trial, the ongoing REDUCER-I European Post-Market study, with over 200 patients currently enrolled with up to 5 years of follow-up, and supportive clinical evidence from multiple peer reviewed publications on Reducer.

29. On January 13, 2020, Neovasc issued a press release with an investor update, stating, in relevant part: "Neovasc submitted a [PMA] to the FDA for approval in the US. The company believes Reducer's clinical evidence to date will support the efficacy and safety profile required for approval of the application in late 2020 or early 2021."

30. On January 15, 2020, the Company issued a press release entitled "Neovasc Receives Administrative Acceptance Review Notification for Premarket Approval Application from FDA for the Neovasc Reducer." Therein, defendant Colen was quoted as saying: "The FDA conducted an administrative acceptance review of our Premarket Approval Application, submitted December 30, 2019, and found it contained all of the necessary elements and information needed to proceed with the filing review."

31. On March 30, 2020, the Company filed its annual report on Form 20-F with the SEC for the period ended December 31, 2019. Therein, Neovasc stated, in relevant part:

> ***Our products are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays, or prevent the receipt of the required approvals to commercialize products.***

> The pre-clinical and clinical trials of any products developed by us and the manufacturing, labeling, sale, distribution, export or import, marketing, advertising and promotion of any of those products are subject to rigorous regulation by federal, provincial, state and local governmental authorities. Our medical devices are principally regulated in the United States by the FDA, in Canada by the Health Canada (particularly, the Therapeutic Products Directorate), in the European Union by the European Medicines Agency ("EMA"), and by other similar regulatory authorities in other jurisdictions. Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling products. Following several widely publicized issues in recent years, the FDA and similar regulatory authorities in other jurisdictions have become increasingly focused on product safety. ***This development has led to, among other things, requests for more clinical trial data, for the inclusion of a significantly higher number of patients in clinical trials and for more detailed analysis of trial results. Consequently, the process of obtaining regulatory approvals, particularly from the FDA, has become more costly, time consuming and challenging than in the past.*** Any product developed by us or our future collaborative partners, if any, must receive all relevant regulatory approvals or clearances from the applicable regulatory authorities before it may be marketed and sold in a particular country.

(Second emphasis added.)

32. On May 26, 2020, Neovasc provided a corporate update in a press release, stating, in relevant part: "[T]he Reducer FDA [PMA] milestones continue to progress, with our '100-day Meeting' recently completed."

33. On June 26, 2020, the Company issued a press release to announce "positive interim results of the REDUCER-I study." Therein, Neovasc stated, in relevant part:

> REDUCER-I is a multi-center, international, three-arm prospective and retrospective observational study enrolling up to 400 patients suffering from refractory angina. The patients included in the study have exhausted other treatment options including drug-therapy and represent a difficult-to-treat population. Today's presentation provided data from 241 patients enrolled in the study, with up to three years follow-up, making it the largest and longest duration Reducer data set presented to date. The primary efficacy endpoint of the study is improvement in chest pain, or angina, as measured by the Canadian Cardiovascular Society ("CCS") grading system.
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> Highlights of the study included:
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> - 70% of patients saw improvement in their symptoms by at least 1 CCS Class that was maintained through 3 years

- 34% of patients saw improvement in their symptoms by at least 2 CCS Classes that was maintained through 3 years
- Prior to treatment, ~70% of patients were CCS Class 3-4, the most severe classes of symptoms
- After treatment with Reducer through 2-year follow-up, ~16% of patients were CCS Class 3-4
- Patients experienced a 91% decrease in emergency department visits from the 12 months prior to baseline compared to 12 months after treatment with Reducer
- Less than 1% of patients experienced a device or procedure related major adverse event

"***We believe the results from the REDUCER-I study demonstrate that for patients suffering from the debilitating effects of refractory angina, Reducer therapy is safe and offers a sustained improvement in symptoms***", said Dr. Verheye. "Today's findings reinforce the results of the COSIRA study published in the New England Journal of Medicine and align with the current European Society of Cardiology Guidelines for the treatment of chronic coronary syndromes."

34. The above statements identified in ¶¶ 24 and 26-33 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (i) Neovasc had overstated the viability of U.S. approval of the Reducer based on its "Breakthrough Device Designation" and prior studies supporting the Reducer's efficacy and safety; (ii) the results of Neovasc's clinical studies used to support approval for the Reducer in the U.S. contained imbalances in missing information present in the control group versus the treatment group, including significant missing information for secondary endpoints but none for the primary endpoint; (iii) the imbalance in missing information indicated that control subjects were aware of their treatment assignment (not blinded) and less inclined to participate in additional data collection; (iv) blinding is critical when studying a placebo-responsive condition such as angina; (v) the lack of blinding assessment made the primary endpoint difficult to interpret; (vi) as a result

of the foregoing, the FDA was reasonably likely to require additional premarket clinical data; (vii) as a result, the Company's PMA for Reducer was unlikely to be approved without additional clinical data; and (viii) as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

The Truth Fully Emerges

35. On October 27, 2020, the Circulatory System Devices Panel of the Medical Devices Advisory Committee to the FDA met to discuss, make recommendations, and vote on information related to Neovasc's PMA. A brief summary of the panel's discussion was issued to the public, which noted concerns with the Company's clinical data, including "that the lack of blinding assessment made the primary endpoint difficult to interpret." As a result, the panel reached a consensus "that additional premarket randomized clinical data was necessary." Specifically, the FDA panel's brief summary stated:

> Panelists were concerned that the sponsor could not explain the imbalance in missing information present in the control group versus the treatment group, or why there was significant missing information for secondary endpoints but none for the primary endpoint. Panelists suggested that the imbalance in missing information could indicate that control subjects aware of their treatment assignment were less inclined to participate in additional data collection. ***The panel concluded that blinding is critical when studying a placebo-responsive condition such as angina and that the lack of blinding assessment made the primary endpoint difficult to interpret.*** They noted that a more objective endpoint would have been helpful to mitigate these concerns.
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> * * *
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> The panel agreed with the concerns cited regarding the small sample size and unpowered secondary endpoints. The panel concluded that without randomization or blinding, the REDUCER I observational study data was of limited use in alleviating these concerns.
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> * * *

> Panelists discussed their concerns for this patient population that is difficult to treat and desperate for options, and how to weigh that against the lack of objective evidence of efficacy. Several panelists were concerned that approval would set a precedent and lead to the availability of multiple unproven therapies, ultimately making treatment decisions more difficult. ***There was consensus from the panel that additional premarket randomized clinical data was necessary.***

(Emphases added.)

36. On October 28, 2020, before the market opened, the Company announced that an FDA advisory panel voted overwhelmingly against the safety and effectiveness of the Reducer. In a press release, Neovasc stated, in relevant part:

> NVCN today announced that the [FDA's] Circulatory System Devices Advisory Panel voted 14 to 4 "in favor" that the Neovasc ReducerTM is safe when used as intended, and voted 1 to 17 "against" on the issue of a reasonable assurance of effectiveness. The third vote was 13 to 3 "against" (2 abstained) on whether the relative benefits outweighed the relative risks.
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> "We would like to thank the FDA, the panel and members of the public that offered their insights during yesterday's Circulatory System Devices Advisory Panel meeting," said Fred Colen, President and Chief Executive Officer of Neovasc. "Clearly, we are disappointed with the meeting's outcome, and we will provide further updates in the coming weeks."
>
> The Reducer is currently under review by the agency for treatment of patients with refractory angina pectoris despite guideline directed medical therapy, who are unsuitable for revascularization by coronary artery bypass grafting or by percutaneous coronary intervention.

37. On this news, the Company's common share price fell $0.77 per share, or 42%, to close at $1.06 per share on October 28, 2020, on unusually heavy trading volume.

38. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

39. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased

or otherwise acquired Neovasc securities during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

40. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Neovasc's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Neovasc shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Neovasc or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

41. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

42. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

43. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Neovasc; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

44. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

45. The market for Neovasc's securities was open, well-developed, and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Neovasc's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Neovasc's securities relying upon the integrity of the market price of the Company's securities and market information relating to Neovasc, and have been damaged thereby.

46. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Neovasc's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Neovasc's business, operations, and prospects as alleged herein.

47. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Neovasc's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

48. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

49. During the Class Period, Plaintiff and the Class purchased Neovasc's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

50. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced

in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Neovasc, their control over, and/or receipt and/or modification of Neovasc's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Neovasc, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

51. The market for Neovasc's securities was open, well-developed, and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Neovasc's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Neovasc's securities and market information relating to Neovasc, and have been damaged thereby.

52. During the Class Period, the artificial inflation of Neovasc's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Neovasc's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Neovasc and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company's shares. Defendants' materially false and/or misleading statements during the Class Period resulted

in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

53. At all relevant times, the market for Neovasc's securities was an efficient market for the following reasons, among others:

(a) Neovasc shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Neovasc filed periodic public reports with the SEC and/or the NASDAQ;

(c) Neovasc regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Neovasc was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

54. As a result of the foregoing, the market for Neovasc's securities promptly digested current information regarding Neovasc from all publicly available sources and reflected such information in Neovasc's share price. Under these circumstances, all purchasers of Neovasc's securities during the Class Period suffered similar injury through their purchase of Neovasc's securities at artificially inflated prices and a presumption of reliance applies.

55. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972),

because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

56. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Neovasc who knew that the statement was false when made.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

57. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

58. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Neovasc's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each defendant, took the actions set forth herein.

59. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Neovasc's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

60. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Neovasc's financial well-being and prospects, as specified herein.

61. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Neovasc's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Neovasc and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

62. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development, and reporting of the Company's internal budgets, plans, projections, and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

63. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Neovasc's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

64. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Neovasc's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Neovasc's securities during the Class Period at artificially high prices and were damaged thereby.

65. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Neovasc was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Neovasc securities,

or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

66. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

67. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

68. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

69. The Individual Defendants acted as controlling persons of Neovasc within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

70. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

71. As set forth above, Neovasc and the Individual Defendants each violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: November 25, 2020

Respectfully submitted,

POMERANTZ LLP

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Attorneys for Plaintiff

CERTIFICATION OF NAMED PLAINTIFF
PURSUANT TO FEDERAL SECURITIES LAWS

The undersigned declares, as to the claims asserted under the federal securities laws, that:

Plaintiff has reviewed the initial complaint filed in this action.

Plaintiff did not purchase and/or acquire the security that is the subject of this action at the direction of Plaintiff's counsel or in order to participate in any private action under the federal securities laws.

Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary. I understand that this is not a claim form, and that my ability to share in any recovery as a member of the class is not dependent upon execution of this Plaintiff Certification.

Plaintiff's transactions in the security that is the subject of this action during the Class Period are as follows **- List additional transactions on Schedule A, if necessary**:

Purchases:

Ticker of Company	Date(s) Purchased	# Shares Purchased	Cost/Share
	01/06/2020	1000	$3.55
NVCN	01/06/2020	800	$3.52
	01/06/2020	100	$3.50
	01/06/2020	1099	$3.58
	01/06/2020	1101	$3.71
	01/08/2020	35	$3.12
	01/14/2020	65	$3.07
	01/28/2020	100	$3.1467
	02/04/2020	195	$2.55
	02/04/2020	105	$2.4795
	02/10/2020	45	$2.4445
	02/26/2020	60	$2.60
	02/26/2020	15	$2.615

Sales:

Ticker of Company	Date(s) Sold	# Shares Sold	Proceeds/Share

During the three (3) years prior to the date of this certification, Plaintiff has not sought to serve or served as a class representative in an action filed under the federal securities laws except for the following (if any):

None

Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 4 day of November, 2020 in (redacted).
City State

(Signature) X DocuSigned by: Daniel Siple C93C4F83F3E74DA...

(Print Name) Daniel Siple
First Last

SCHEDULE A

Purchases:

Ticker of Company	Date(s) Purchased	# Shares Purchased	Cost/Share
	03/09/2020	40	$2.44
NVCN	03/09/2020	40	$2.52
	03/11/2020	100	$2.25
	03/18/2020	60	$1.675
	03/23/2020	130	$1.5156
	03/31/2020	70	$1.479
	06/12/2020	80	$2.575
	07/15/2020	85	$2.4194
	08/10/2020	85	$2.27
	08/10/2020	90	$2.30
	10/02/2020	100	$2.20
	10/27/2020	100	$1.9769

Sales:

Ticker of Company	Date(s) Sold	# Shares Sold	Proceeds/Share